Original Article

Balloon Angioplasty as a Modality to Treat Children with Pulmonary Stenosis Secondary to Complex Congenital Heart Diseases

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Abstract

Background: Pulmonary stenosis is common in children with complex congenital heart diseases. Proper management of this problem, especially postoperatively, is still controversial. This study was designed to assess the rate and determinants of success or failure of balloon angioplasty for such lesions.

Methods: Clinical and hemodynamic data from 40 pediatric patients (24 boys and 16 girls) with complex congenital heart diseases who underwent balloon angioplasty were reviewed retrospectively from January 2012 to December 2016. Patients were divided into four groups according to the site of stenosis, which included pulmonary valve stenosis (PVS), valved conduit stenosis, pulmonary artery stenosis (PAS), and supravalvular pulmonary stenosis (SVPS). Success rates were calculated according to defined criteria for initial success and favorable clinical impacts, and comparison between the successful subgroup and the unsuccessful subgroups was analyzed.

Results: Grouped by the site of stenosis, initial success rates varied from 40.0% to 52.4% with the greatest success being seen in the PVS group, followed by the PAS group and SVPS group. In the PVS group and the PAS group, there was no statistical difference among age at dilation, postoperative interval, balloon/stenosis ratio, or pressure gradient predilation between the successful and the unsuccessful subgroups. Favorable clinical impacts included success rates of balloon angioplasty in the SVPS group, which was best (100%), followed by the PVS group (90.9%) and the PAS group (85.7%). There were a total of two transient complications (5.0%).

Conclusions: Balloon angioplasty was proven to be a safe and useful modality in children with complex congenital heart diseases and postoperative pulmonary stenosis, which should be the initial therapeutic modality in selected patients.

Key words: Balloon Angioplasty; Complex Congenital Heart Disease; Pulmonary Stenosis

Introduction

Pulmonary stenosis is common in children with complex congenital heart diseases,[1,2] which makes management complicated, especially in postoperative patients, for both surgeons and physicians. Management of this problem is still controversial. Surgery to directly relieve these lesions is difficult and often ineffective, with a success rate of approximately 30%.[3,4] Furthermore, in growing children with complex congenital heart diseases, where physiological and psychological influences should be as minimized, repeat surgery would be necessary. However, balloon angioplasty and the introduction of endovascular stents provide more optimal options.[5-7] Previous studies of balloon angioplasty showed relatively higher initial success rates (50–60%) with low complications (6–10%). With improved techniques and wider applications, balloon angioplasty for pulmonary (artery) stenosis has become a reliable alternative to surgical management in many centers around the world.[8,9] The comprehensive benefits of balloon dilation during the postprocedure follow-up provided

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positive clinical impacts and recommendations. Moreover, several hospitals in developed countries demonstrated clinical success rates from 35% to >50%.[5,10]

In China, the use of balloon angioplasty has been less popular than in other countries. This lack of popularity is not centered on the technology, equipment, or regions where it is used. However, it results in fewer relevant clinical studies and case reports of children with complex congenital heart diseases and pulmonary stenosis being treated with balloon angioplasty. Here, we reviewed the procedural success rates of 41 balloon angioplasties (40 patients) for pulmonary stenosis and compared these success rates with the clinical impact on subsequent management.

Methods

Ethical approval

The study was approved by the Ethics Committee of Beijing Anzhen Hospital, and written informed consent was obtained before data collection from the parents of each patient.

Participants

Between January 2012 and December 2016, a total of 40 pediatric patients (24 boys and 16 girls) in our department underwent balloon dilation of postoperative complex congenital heart diseases were enrolled in the present study.

Inclusion criteria included (1) patients with complex congenital heart disease and had undergone palliated or corrected surgery before balloon dilation; (2) age not more than 18 years old; and (3) patients performed balloon angioplasty because of one or more of the following: (a) right ventricular pressure >60% of aortic pressure; (b) distal pulmonary artery stenosis (PAS), not easily accessed by a surgical approach, that served as a prelude to the definitive surgical repair of an underlying lesion; and (c) cardiovascular symptoms such as increased cyanosis or exercise intolerance.

Exclusion criteria included (1) patients with complex congenital disease but had never undergone any previous surgery and (2) patients aged >18 years.

Balloon dilation technique

Vascular access was established percutaneously, using femoral vessels. A hemodynamic evaluation was initially performed to measure the pressure of the right heart, left heart, and pulmonary systems. Then, right ventricular and pulmonary artery angiograms were performed in the frontal and lateral projections, which helped identify the precise site of stenosis. This was followed by insertion of a 5F or 6F end-hole catheter that was advanced to a pulmonary artery branch (usually the left), which allowed a 260 cm long, 0.035 inch exchange guide wire (Cordis Corporation, USA), to be positioned in the pulmonary artery branch as distally as possible.

The initial balloon diameter was selected to be 1.2–1.4 times the pulmonary valve diameter in patients with pulmonary valve stenosis (PVS), and to be about twice the narrowest site in other patients with PAS or supravalvular pulmonary stenosis (SVPS) (the actual diameters ranged from 1.40 to 5.50 [mean 3.64 ± 1.08] times of the measured stenotic segment). The balloon catheter was advanced over the wire, and its midportion was positioned at the pulmonary valve or the narrowest area in the pulmonary artery. The location was confirmed fluoroscopically with low-pressure inflation.

Under continuous fluoroscopic, electrocardiographic, and systemic pressure monitoring, the balloon was inflated until the "waist" disappeared or until the maximal allowable pressure was applied for 5–10 s, after which the balloon was rapidly deflated. If no waist was seen, the next largest balloon size was chosen; however, a balloon was never larger than the diameter of the conduit. After dilation, the balloon catheter was removed, pressure and oxygen saturation measurements were repeated, and a postdilation right ventriculogram or pulmonary artery angiogram using a pigtail catheter was performed in most patients.

Previous criteria for initial procedural success were defined by at least one of the followings: an increase in vessel diameter by 50% of the predilation diameter, a 20% decrease in right-to-left ventricular pressure or in the aortic systolic pressure ratio, or a 50% decrease in the peak-to-peak pressure gradient over the stenotic area.

Follow-up and criteria for clinical success

The mean follow-up duration was 2.73 ± 1.34 years (range 0.45–4.50 years). All patients underwent clinical evaluation and two-dimensional color Doppler studies.

Clinical success, as recorded in follow-up, was defined as one or more following: (1) resolution of stenosis and avoidance of surgical intervention; (2) optimization of future surgical intervention, as judged by one of the two criteria: (a) pulmonary artery anatomy or pressure that became suitable for surgical repair in patients, who previously had pulmonary artery anatomies or pressures for which surgical repair was contraindicated; and (b) obviating the need for surgical intervention in the areas treated with balloon angioplasty during the succeeding surgical repair; and (3) alleviation of symptoms due to right heart dysfunction, improvement in oxygen saturation, or both.

Statistical analysis

Results are expressed as mean values ± standard deviation (SD). Group comparisons were performed using the two-tailed paired *t*-test. Statistical analyses were performed using the SPSS version 18.0 (SPSS Inc., Chicago, IL, USA). Significance was defined as $P < 0.05$.

Results

Patient characteristics

Tetralogy of Fallot (TOF) was the most frequent heart malformation (70%). Balloon angioplasty was performed to relieve pulmonary stenotic sites, and the mean age at dilation was 5.85 ± 4.59 years (range from 1.11 to 18.00 years),

the median systemic oxygen saturation was 85% (range from 65% to 100%), and the interval between surgery and balloon dilation was 4.33 ± 3.61 years (range from 0.50 to 17.50 years). Forty patients were grouped into four groups by the site of stenosis. While the left ventricular ejection fraction in all patients was normal, 21 patients complained of symptoms such as edema, exercise intolerance, and aggravated cyanosis. Moderate tricuspid regurgitation was also found in 25 patients [Table 1].

Pulmonary valve stenosis

The pulmonary valve was stenosed in 21 patients, who attempted balloon dilation in age from 1.30 to 18.00 years (mean 5.28 ± 4.64 years) and 0.50–17.50 years (mean 3.94 ± 3.02 years) after the previous surgery. The pulmonary annular diameter was 5.50–13.10 mm. Primary congenital heart defects included TOF (n = 18), transposition of the great arteries with ventricular septal defects and pulmonary stenosis (n = 1), double outlet of right ventricle (DORV) with pulmonary stenosis (n = 1), and single ventricle with pulmonary stenosis (n = 1).

Valved conduit stenosis

The conduit was stenosed in one patient, who underwent balloon dilation 11 years after insertion of the conduit at 7 years of age. The conduit was 12 mm in diameter, and the repaired congenital heart defect was pulmonary atresia.

Pulmonary artery stenosis

Stenosis was present at the pulmonary artery in 13 patients, who underwent balloon dilation. The ages of these patients ranged from 1.90 to 12 years (mean 5.92 ± 3.09 years), and they underwent corrective or palliate surgeries from 1 to 10 years (mean 4.69 ± 2.70 years) earlier.

Supravalvular pulmonary stenosis

This stenosis was present in the remaining five patients, who ranged in age from 1.11 to 8.00 years (mean 5.04 ± 3.48 years) during the balloon dilation procedure. Four of these patients had undergone a corrective surgery from 1.17 to 6.00 years (mean 2.75 ± 2.30 years) earlier, while one had undergone a Blalock–Taussig shunt 7 years before.

Initial results

Forty patients underwent a total of 41 balloon angioplasties, with a total initial success rate of 48.8% (20 of 41 procedures). Two balloon angioplasties were performed in one case of TOF, in which the patient underwent a modified central Blalock–Taussig shunt, but still had bilateral PAS; however, both procedures were unsuccessful. Diameter differences of the stenotic segments and other hemodynamic parameters of the groups are shown in Figure 1.

Pulmonary valve stenosis

Hemodynamic data of the 21 patients in the PVS group are presented in Table 2. Using procedural criteria for initial success, 52.4% (11 of 21) of the balloon dilations were successful. In these 11 patients, the mean decrease in the systolic right ventricular/aortic pressure ratio was 0.86 ± 0.08 to 0.53 ± 0.06. The mean decrease in the peak systolic pressure gradient over the pulmonary valve was 81.45 ± 17.05 mmHg (1 mmHg = 0.133 kPa) to 35.82 ± 14.63 mmHg. The mean opening diameter of the pulmonary valve increased from 5.00 ± 1.10 mm to 8.22 ± 1.62 mm. The mean balloon/annulus diameter ratio was 1.43 ± 0.25 (range 1.14–1.70). Mean age at dilation was 3.83 ± 3.32 years, and the mean interval to postoperative procedure was 2.52 ± 2.43 years.

Of the ten patients with an initial unsuccessful procedure, mean age at dilation was 6.88 ± 5.50 years, and the mean interval to postoperative procedure was 5.56 ± 5.11 years. The mean balloon/annulus diameter ratio was 1.37 ± 0.43 (range 0.86–2.40).

The mean age at dilation in the successful subgroup appeared to be younger and to have a greater mean interval to postoperative procedure than the unsuccessful subgroup, but statistical differences did not exist between these two

Table 1: Clinical characteristics of patients with pulmonary stenosis secondary to complex congenital heart diseases, n = 40

Group	Age at dilation (years)	Interval postoperation (years)	CHD, n							TR (moderate), n
			TOF	DORV	TGA	SV	PA	TA	ALCAPA	
PVS (n = 21)	5.28 ± 4.64	3.94 ± 3.02	18	1	1	1	–	–	–	14
PAS (n = 13)	5.92 ± 3.09	4.69 ± 2.70	9	–	–	1	2	1	–	8
SVPS (n = 5)	5.04 ± 3.48	3.60 ± 2.32	1	2	1	–	–	–	1	2
VCS (n = 1)	18.00	11.00	–	–	–	–	1	–	–	1

Group	Procedure time (min)	Previous operation, n			Symptom, n		
		Correction	B-T	Glenn	Edema	Exercise intolerance	Aggravated cyanosis
PVS (n = 21)	92.38 ± 26.25	4	13	4	1	2	3
PAS (n = 13)	95.70 ± 24.41	8	4	1	1	4	4
SVPS (n = 5)	98.02 ± 24.92	4	1	–	–	4	1
VCS (n = 1)	125.00	1	–	–	–	1	–

–: Not applicable; TOF: Tetralogy of Fallot; DORV: Double outlet of right ventricle; PS: Pulmonary stenosis; TGA: Transposition of great arteries; SV: Single ventricle; PA: Pulmonary atresia; TA: Truncus arteriosus; ALCAPA: Anomalous origin of the left coronary artery from the pulmonary artery; PVS: Pulmonary valve stenosis; PAS: Pulmonary artery stenosis; SVPS: Supravalvular pulmonary stenosis; VCS: Valved conduit stenosis; CHD: Congenital heart disease; TR: Tricuspid regurgitation; B-T: Blalock–Taussig.

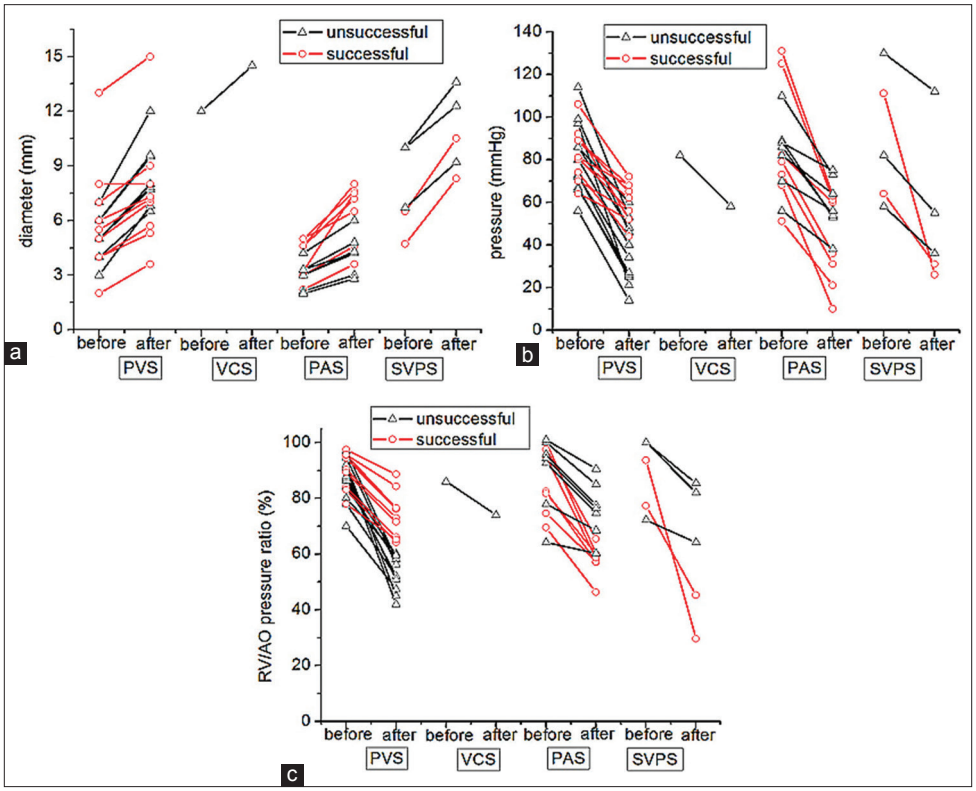

Figure 1: Comparison of parameters before and after balloon dilation between successful and unsuccessful subgroups in all four groups. (a) Diameter differences of stenotic segments before and after balloon dilation between successful and unsuccessful subgroups in all four groups. (b) Pressure differences over stenotic segments before and after balloon dilation between successful and unsuccessful subgroups in all four groups. (c) RV/AO pressure ratio before and after balloon dilation between successful and unsuccessful subgroups in all four groups. PVS: Pulmonary valve stenosis; PAS: Pulmonary artery stenosis; SVPS: Supravalvular pulmonary stenosis; VCS: Valved conduit stenosis; RV: Right ventricle; AO: Aorta.

Table 2: Hemodynamic data of 21 patients in the pulmonary valve stenosis group

Patient number	Balloon/ annulus ratio	Opening diameter (mm)	Opening diameter after dilation (mm)	Pre-PG (mmHg)	Post-PG (mmHg)	Pre-RV/AO pressure ratio	Post-RV/AO pressure ratio
1*	1.30	5.00	8.00	86	60	0.80	0.60
2*	1.30	5.00	7.70	56	14	0.78	0.52
3*	1.14	4.00	6.50	67	25	0.97	0.58
4*	1.50	5.00	8.00	73	26	0.91	0.42
5*	1.26	6.00	9.50	97	21	0.92	0.45
6*	2.00	4.00	6.50	66	27	0.86	0.52
7*	1.25	5.00	7.80	80	40	0.84	0.58
8*	1.50	5.00	8.00	86	48	0.87	0.60
9*	1.50	3.00	6.80	72	34	0.70	0.47
10*	1.70	6.00	9.60	114	53	0.95	0.56
11*	1.30	7.00	12.00	99	46	0.88	0.51
12†	1.20	2.00	3.60	92	52	0.90	0.73
13†	1.50	5.00	7.00	89	65	0.94	0.76
14†	1.25	5.50	7.20	89	68	0.84	0.66
15†	1.30	4.00	5.70	74	44	0.95	0.76
16†	2.40	4.00	5.30	81	68	0.89	0.72
17†	1.50	7.00	9.00	80	62	0.83	0.64
18†	1.50	8.00	8.00	106	72	0.96	0.77
19†	0.90	7.00	9.00	70	56	0.97	0.89
20†	1.25	6.00	7.30	64	52	0.96	0.84
21†	0.86	13.00	15.00	81	56	0.78	0.65

1 mmHg = 0.133 kPa. *Successful subgroup; †Unsuccessful subgroup. PG: Pressure gradient; RV: Right ventricle; AO: Aorta.

parameters ($P > 0.05$). There were also no statistical differences found in the balloon/annulus diameter ratio ($P > 0.05$) or the peak systolic pressure gradient predilation over the pulmonary valve ($P > 0.05$) between the successful subgroup and the unsuccessful subgroup (comparisons of these parameters between the initial successful and unsuccessful subgroups are shown in Table 3).

Valved conduit stenosis

An 18-year-old boy with pulmonary atresia, who underwent corrective surgery with a 20-mm homograft valved conduit 11 years earlier, presented with exercise intolerance. Balloon angioplasty of the conduit was performed, and only a minimal increase was seen at the stenotic site, from 12 mm to 14.50 mm, with a decrease in the right ventricle (RV)/aorta pressure ratio from 0.86 to 0.74. This procedure was thus considered unsuccessful according to our criteria.

Pulmonary artery stenosis

Hemodynamic data from this group of 13 patients (14 procedures) are presented in Table 4. In this group, 50.0% (7 of 14) of the balloon dilations were successful. In these seven patients, the mean decrease in the systolic right ventricular/aortic pressure ratio was 0.86 ± 0.12 to 0.58 ± 0.06. The mean peak systolic pressure gradient over the stenotic segment decreased from 87.00 ± 29.78 mmHg to 40.29 ± 21.32 mmHg. The mean diameter of the stenotic pulmonary artery increased from 3.94 ± 1.12 mm to 6.43 ± 1.68 mm. The mean balloon/stenotic diameter ratio was 3.87 ± 1.51 (range 1.40–5.50). Mean age at dilation was 7.13 ± 2.83 years, and the mean interval to postoperative procedure was 5.62 ± 2.18 years. Images of severe right PAS in a girl with repaired TOF before and after balloon dilation are demonstrated in Figure 2.

Of the other seven initial unsuccessful procedures, one male patient with TOF had two balloon dilations performed, but unfortunately, both failed. In this group, the mean age at dilation and mean interval to postoperative procedure were both less than that of the successful subgroup, and the mean balloon/stenotic diameter ratio was higher. However, no statistical differences were seen in any parameters ($P > 0.05$). The peak systolic pressure gradient predilation over the stenotic segment in this subgroup seemed more severe than that of the successful subgroup, but no statistics differences existed ($P > 0.05$) (comparisons of these parameters between two subgroups are shown in Table 3).

Supravalvular pulmonary stenosis

Hemodynamic data from this group of five patients are presented in Table 5. Two of the five (40.0%) patients met our success criteria. One patient was a 1.11-year-old boy who was diagnosed by anomalous origin of the left coronary

Table 3: Comparisons of age, postoperative intervals, balloon/stenosis ratio and pressure gradient predilation between subgroups in the pulmonary valve stenosis group and the pulmonary artery stenosis group

Variable	PVS group		*t*	*P*	PAS group		*t*	*P*
	Successful subgroup (*n*=11)	Unsuccessful subgroup (*n*=10)			Successful subgroup (*n*=7)	Unsuccessful subgroup (*n*=7)		
Age at dilation (years)	3.83 ± 3.32	6.88 ± 5.50	−1.56	0.14	7.13 ± 2.83	4.71 ± 3.04	1.54	0.15
Interval postoperation (years)	2.52 ± 2.43	5.56 ± 5.11	−1.70	0.10	5.62 ± 2.18	3.76 ± 3.01	1.32	0.21
Balloon/stenosis diameter ratio	1.43 ± 0.25	1.37 ± 0.43	0.44	0.67	3.87 ± 1.51	3.96 ± 0.41	−0.15	0.89
Pressure gradient predilation (mmHg)	81.45 ± 17.05	82.60 ± 12.06	0.31	0.76	87.00 ± 29.78	83.00 ± 16.82	0.31	0.76

1 mmHg = 0.133 kPa. PVS: Pulmonary valve stenosis; PAS: Pulmonary artery stenosis.

Table 4: Hemodynamic data of 13 patients (14 procedures) in the pulmonary artery stenosis group

Patient number	Balloon/stenotic site ratio	Opening diameter (mm)	Opening diameter after dilation (mm)	Pre-PG (mmHg)	Post-PG (mmHg)	Pre-RV/AO pressure ratio	Post-RV/AO pressure ratio
1*	1.40	5.00	6.50	82	60	0.83	0.57
2*	2.20	3.00	4.60	125	61	1.00	0.60
3*	4.00	5.00	7.60	68	10	0.75	0.57
4*	5.50	2.20	3.60	51	21	0.70	0.46
5*	5.00	4.60	7.20	79	36	0.82	0.60
6*	4.70	3.20	7.50	73	31	0.98	0.65
7*	4.30	4.60	8.00	131	63	0.95	0.59
8†	3.60	4.20	6.00	110	73	1.00	0.85
9†	3.40	3.30	4.20	89	53	0.93	0.75
10†	4.00	3.00	4.20	56	38	0.78	0.69
11†	4.70	2.11	3.00	88	75	1.01	0.91
12†	4.00	3.00	4.30	82	64	0.64	0.60
13†	4.00	2.00	2.80	86	54	0.96	0.78
13†	4.00	3.30	4.80	70	56	0.94	0.76

1 mmHg = 0.133 kPa. *Successful subgroup; †Unsuccessful subgroup. PG: Pressure gradient; RV: Right ventricle; AO: Aorta.

Table 5: Hemodynamic data of five patients in the supravalvular pulmonary stenosis group

Patient number	Balloon/stenotic site ratio	Opening diameter (mm)	Opening diameter after dilation (mm)	Pre-PG (mmHg)	Post-PG (mmHg)	Pre-RV/AO pressure ratio	Post-RV/AO pressure ratio
1*	3.10	6.50	10.50	64	31	0.77	0.45
2*	3.20	4.70	8.30	111	26	0.94	0.30
3†	3.70	6.70	9.20	58	36	0.72	0.64
4†	1.80	10.00	12.30	82	55	1.00	0.82
5†	2.50	10.00	13.60	130	112	1.00	0.85

1 mmHg = 0.133 kPa. *Successful subgroup; †Unsuccessful subgroup. PG: Pressure gradient; RV: Right ventricle; AO: Aorta.

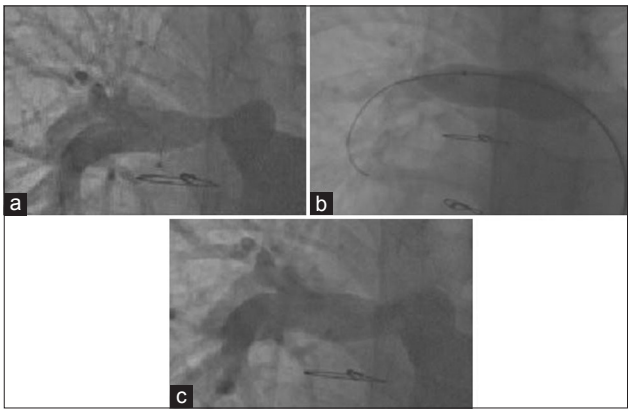

Figure 2: Angiogram of severe right pulmonary artery stenosis before, during and after balloon dilation in a girl with repaired tetralogy of Fallot. All angiograms were obtained in the posteroanterior projections. (a) Severe right pulmonary artery stenosis before balloon dilation. (b) Balloon dilation across the stenosis site of the right pulmonary artery. (c) Diameter of the stenosed right pulmonary artery increased after successful balloon angioplasty.

artery from the pulmonary artery, who underwent surgical repair 1.25 years before the current balloon angioplasty. After balloon angioplasty, the diameter of the most stenotic area in the supravalvular pulmonary system increased from 6.50 mm to 10.50 mm, and the peak systolic pressure gradient decreased from 64 mmHg to 31 mmHg. In addition, the symptom of dyspnea after exercise was alleviated.

Another patient was a 1.4-year-old girl with DORV, had a surgical repair performed 1.17 years before the current balloon angioplasty. After balloon angioplasty, the diameter of the most stenotic area in the supravalvular pulmonary system increased from 4.70 mm to 8.30 mm, and the peak systolic pressure gradient decreased from 111 mmHg to 26 mmHg.

When compared with the successful subgroup, it seemed that the age at dilation of the unsuccessful subgroup was older, and the interval to postoperative procedure was longer.

Follow-up and clinical outcomes

All patients were followed up for a period ranging from 0.45 to 4.50 years, which examined both early and late clinical impacts, resulting in comprehensive assessments.

Pulmonary valve stenosis

Balloon angioplasty had a favorable clinical impact in 10 of the 11 initial successful procedures (90.9%). In 8 patients with TOF, who had undergone a palliative Blalock–Taussig shunt, balloon angioplasty improved the forward pulmonary blood supply, helped develop the pulmonary artery, and allowed corrective surgeries to be performed by 0.10–1.10 years. In two patients with repaired surgery, resolution of the stenosis was almost complete, and further intervention was unnecessary.

Fortunately, we also found five patients (50.0%) in the unsuccessful subgroup with TOF, who underwent the palliative Blalock–Taussig shunt or the Glenn operation that benefited from balloon angioplasty. These patients underwent corrective surgical repairs by 1–2 years. In some ways, it can be surmised that balloon angioplasty optimized the surgical intervention of these patients as the total favorable clinical success rate in this group was 71.4%.

Valved conduit stenosis

Balloon angioplasty failed in the patient of this group, as only minimal decreases in pressure gradients and minimal relief of symptoms were found. Eleven months after the balloon angioplasty, this patient had a surgical procedure to place a larger conduit.

Pulmonary artery stenosis

Balloon angioplasty had a favorable clinical impact in six of the seven initially successful patients (85.7%), of which four patients who received reparative cardiovascular surgeries had an almost complete resolution of stenosis with further intervention unnecessary. In another two patients with reparative surgery, symptoms relating to right heart dysfunction were alleviated, which postponed further interventions.

In the initial unsuccessful subgroup, one female patient had received reparative TOF surgery 2 years before she underwent balloon angioplasty. The dilation procedure was partially effective as the diameter of the stenotic branch pulmonary artery increased from 3.30 mm to 4.20 mm, but the gradient over the stenotic site decreased <50%. During a 3-year follow-up visit, the gradient had worsened, symptoms became more obvious, and she finally received an endovascular stent intervention to resolve the stenosis.

One patient with TOF in the unsuccessful subgroup underwent two balloon angioplasty procedures. Two years after the Blalock–Taussig shunt was performed, the first balloon angioplasty was performed at 2.70 years of age due to bifurcation stenosis, which provided a small benefit. One

year later, the second balloon angioplasty was performed, although the balloon diameter was increased from three to four times the stenosis diameter. This procedure partially decreased the gradient, RV pressure, and symptoms. For a patient who had a deficient pulmonary artery, no corrective surgery was available. The parents of this patient refused further palliative surgery, but the patient has been consistently followed.

Supravalvular pulmonary stenosis

During the follow-up period, the two patients who had initial success with balloon angioplasty, and were clinically stable, required no further interventions.

Two patients in the unsuccessful subgroup who had surgically repaired TOF were notified that they needed another surgery, but the parents were hesitant because of the negative physiologic and psychological side effects.

Complications

There were two transient complications (5%). Two patients developed femoral vein thrombosis that resolved after 96 h of treatment with low-molecular-weight heparin. And, there was no early or late mortality.

Discussion

Children with complex congenital heart diseases are often confronted with added problems, especially cardiac malformations that remain following the first surgeries. Pulmonary stenosis is one of the malformations seen in postoperative patients. To avoid the risks of surgery, such as thoracoscopy and cardiopulmonary bypass, the less expensive and less invasive therapy balloon angioplasty has been accepted treatment.[11] The present study summarizes our institutional experience with comprehensive balloon angioplasty to treat pulmonary stenosis in forty patients with complex congenital heart disease.

Indications to perform balloon angioplasties were decided by evaluating the symptoms, signs, and important hemodynamic or imaging outcomes of each patient.[11-13] Patients in this study met one or more of the indications. Our current recommendation is to perform diagnostic cardiac catheterization, followed by balloon intervention, if necessary, in all the patients with complex congenital heart diseases.

Balloon dilation is very popular and is proven to be safe and effective in long-term studies using balloon dilation before surgical intervention for treatment of TOF.[14-16] It was shown that successful dilation of the pulmonary valve increases the diameter of the pulmonary valve and improves antegrade pulmonary blood flow, inducing growth of pulmonary arteries and ameliorating a patient's anatomic and physiologic preoperative status.[17,18] In some cases, balloon angioplasty may even be an alternative to the Blalock–Taussig shunt.[19] Although using presurgical balloon dilation to avoid a transannular patch at the time of corrective surgery remains controversial,[14,20,21] some studies demonstrate that the integrity and function of the pulmonary valve should be preserved in selected patients using concomitant balloon dilation during the early repair of TOF.[16,22]

In our study, 28 patients (70.0%) with postsurgical TOF were studied and 18 underwent pulmonary balloon angioplasty. Among these patients, 10 had initial success according to our criteria, and 13 patients, who had undergone the palliative Blalock–Taussig shunt procedure, had complete correction during the follow-up of this study. Experts[14,15] have explained this correction as the symmetric increase in antegrade blood flow after dilation that results in unchanged pulmonary arterial dimensions immediately after balloon dilation, but which can then be seen at follow-up visits.

When surgical repair of PAS is disappointing,[3] due to inaccessible distal stenotic sites, balloon angioplasty can be an effective alternative, with success rates of 50–60%.[8,10] Clinical success rates of balloon interventions were better estimated by taking into account both follow-up visits and clinical results. Through literature reviews,[5,10] it was found that, despite the "initial" success rate of 53–56%, varied clinical management influenced the success in 35–89% of patients.

Grouped by the site of stenosis, initial success rates of our research varied from 40.0% to 52.4%, with the PVS group having the best results followed by the PAS group and the SVPS group. As to the favorable clinical impacts of balloon angioplasty, success rates of the SVPS group had the greatest response (100%), followed by the PVS group (90.9%) and the PAS group (85.7%). We found that the success rate changed with different stenotic sites, which may be associated with the mechanism by which balloon angioplasty operates. Experimental studies indicate that balloon angioplasty works by tearing part or all of the vascular intima and media, creating a large area of vascular remodeling and healing, which has been confirmed by both clinical and pathologic research.[4,23] Due to a limited number of patients, we could not differentiate the exact relationship between the success rate and the stenotic site.

Ring *et al*.[4] suggested that the success rates for pulmonary artery balloon angioplasty higher in younger than in older children, which was supported by Nakanishi *et al*.[24] Unfortunately, in our study, age did not differ significantly between the successful subgroup and the unsuccessful subgroup for the PVS and the PAS groups, as was also reported by Rothman *et al*.[7] Furthermore, previous experience showed that the interval between surgical operation and balloon angioplasty, rather than age at dilation, was a more important determinant of the success or failure of the intervention.[5] However, we could not show a statistical difference in the successful and unsuccessful subgroups. Since results can be influenced by a number of procedures and factors, further research is needed to confirm our findings. As most pulmonary arterial growth occurs before 2 years of age,[25] balloon dilation is recommended at a relatively young age.[7]

Taking the diameter of balloon angioplasty-to-stenotic site ratio into account, there was no significant difference between the successful and unsuccessful subgroups of the PVS and PAS groups in our study, conforming to the report.[12] While the ratio was not an independent determinant of success rates, it was still significant. It was suggested that the balloon-to-annulus ratio should be close to 1.5 and not larger than 2 to get the benefit of balloon dilation in TOF, and to avoid the possible damaging effect of larger balloons.[26] Concerning PAS, the initial balloon size should be two to four times the diameter of the stenosed segment and should not exceed 1.7 times the pulmonary annulus diameter.[27]

Our study has several limitations that should be mentioned. First, this study was based on retrospective data from a single center and, therefore, the number of patients in this study was limited. Second, a total of forty patients in this study were placed into four groups by the variable location of the stenotic sites to make analyses easier. Moreover, the mechanism of balloon dilation was different with each kind of stenosis. Thus, the patients in each group was small in number and heterogeneous, which made results difficult to compare.

In conclusion, despite the limited number of patients and experiences in this study, the success rates in our study were comparable to previous reports from other countries, and we had only a few complications. Balloon angioplasty was confirmed to be a safe and useful modality. Children with postoperative complex congenital heart diseases can benefit by avoiding or postponing surgical intervention. Balloon dilation should be the initial treatment in selected patients, and the success rate was determined by multiple factors. The dilation should be performed at earlier time points and with appropriate balloon diameters to achieve a better success rate.

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Conflicts of interest

There are no conflicts of interest.

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